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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,657	09/18/2001	Richard E. Wooley	U022 1020.1	1163
26389	7590	11/16/2005		
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800 SEATTLE, WA 98101-2347			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,657

Applicant(s)

WOOLEY ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/21/05
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination dated 8/31/05.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1,2,5,7,8,12-15,18-22, and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Raad et al (USPN 6,165,484 hereafter '484) and Cuny et al (USPN 6,207,679 hereafter '679). The claims are drawn to a method of inhibiting the proliferation of a bacterial infection in a skin or mucosal injury by applying a formulation comprising an antibacterial agent and a chelating agent working synergistically.

4. The '484 patent teaches a methods of treating bacterial and fungal infections topically by applying a composition comprising antibacterial/fungal agents working synergistically with chelating agents such as EDTA and active agents such as amphotericin (col. 8, lin. 19-30; col. 14, lin. 25-33 and 58-67). The dosage forms though preferably intravenous, include topical, oral, nasal, buccal, rectal, and vaginal (col. 16, lin. 25-32). The dosage forms include carriers, solvents and an aqueous medium, as well as common oral excipients like mannitol, lactose and starch (col. 15, lin. 50-col. 17, lin. 36). The fungal infections treated by the invention are

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assessed by one of ordinary skill and treated according to the patients' body weight, resistance to medication and other factors that would be routine to one of ordinary skill in the art to ascertain. The reference though using traditional antibacterial compounds to treat fungal infections is silent to the treatment of bacterial infections.

5. The '679 patent teaches the use of antimicrobial agents in the treatment of infections (bacterial/fungal) in wounds such as burns, ulcers, scrapes and bruises (abstract, col. 34, lin. 40-55). The formulations can be used to sterilize medical devices or treat bacterial or fungal infections on internal mucosa, both orally and vaginally (*Ibid.*). Formulations include solutions, elixirs and mouthwashes (col. 38, lin. 46-57). The formulation is effective against both Gram-positive and negative bacterial genus such as *Pseudomonas* and *Staphylococcus* (col. 32, lin. 17-39). The formulation comprises various antimicrobial agents such as penicillins, amino glycosides, and cephalosporins along with carriers and chelators such as EDTA (col. 36, lin. 7-16; col. 38, lin. 19-20). A skilled artisan would have been motivated by these teachings to administer the formulation of '484 to the skin for wound treatment as taught by '679.

6. With these things in mind one of ordinary skill in the art would have been motivated to follow the teachings of '679 to combine biocidal compounds such as those found in both '679 and '484 in order to treat Gram-positive or negative bacterial infections. The '484 teaches the importance of a synergistic relationship between the chelator and the biocide, while the '679 teaches the varying methods of application. The minimum inhibitory concentration (MIC) for each compound would be known by one of ordinary skill in the art as shown in the '679 patent. It would have been obvious to follow the suggestions of '679 and '484 in order to topically treat bacterial infections with an expected result of a method of treating infected wounds.

7. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Raad et al (USPN 6,165,484 hereafter '484), Cuny et al (USPN 6,207,679 hereafter '679) and Raad et al (USPN 5,688,516 hereafter '516). The claims are drawn to a method of treating a bacterial infection with a composition comprising biocidal agents and chelators.

8. As discussed above the combination of the '484 and '679 teach methods of treating various skin injuries and with biocidal formulations. The teachings are however silent to the inclusion of the particular tetracycline claimed by applicant or the specific chelator although the substitution of these compounds would be well within the limits of one of ordinary skill in the art, as shown in the '516 patent.

9. The '516 patent discloses a method of treating Gram positive and negative bacterial infections by applying a composition of chelating agents such as EDTA and triethylene tetramine dihydrochloride and various anti-bacterial agents including oxytetracycline (col. 4, lin. 31 – 53; col. 5, lin. 37-53). One of ordinary skill in the art would have been motivated to include the chelators or tetracycline of the '516 patent in order to treat a wider range of infections.

10. With these things in mind, one of ordinary skill in the art would have been motivated to combine the compounds of the '516 patent into the combination of '679 and '484 in order to treat a wider range of bacterial infections. It would have been obvious to combine the teachings with an expected result of a topical wound healing formulation capable of treating a wider range of infections.

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11. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Raad et al (USPN 6,165,484 hereafter '484), Cuny et al (USPN 6,207,679 hereafter '679) and Kruse et al (USPN 5,646,151 hereafter '151). The claims are drawn to a method of treating a bacterial infection with a topical biocidal formulation comprising specific antibacterial agents.

12. As discussed above the combination of the '484 and '679 patents provide a method of treating various surface wounds with a topical biocidal formulation. The combination of teachings however is silent to the inclusion of the specific biocides recited in the claims. However the inclusion of the compounds into the formulation of the combination would be well within the level of skill in the art, as shown in the '151 patent.

13. The '151 patent discloses topical formulations comprising chelating agents such as EDTA and antibiotic agents such as neomycin, amikacin and tetracyclines (col.33, lin. 3-38; col. 34, lin. 25-48; col. 41, lin. 59-col. 43, lin. 54). The reference establishes the knowledge in the art of combining chelating agents and antibiotic/fungal agents in order to treat skin injuries topically. A skilled artisan would be motivated to include the antibiotics of the '151 patent in order to treat a wider range of bacterial infections.

14. With these things in mind, one of ordinary skill in the art would have been motivated to combine the compounds of the '151 patent into the combination of '679 and '484 in order to treat a wider range of bacterial infections. It would have been obvious to combine the teachings with an expected result of a topical wound healing formulation capable of treating a wider range of infections.

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Response to Arguments

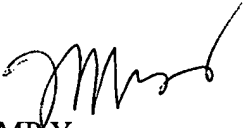
15. Applicant's arguments with respect to claims 1,2,5-15,18-22, and 56-62 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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